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DRUG DISCOVERY

FDA approved drugs – June 2013

Brithvi V

Department of Pharmaceutical Technology, Anna University, BIT Campus, Trichy, Tamil Nadu, India

Correspondence to: Department of Pharmaceutical Technology, Anna University, BIT Campus, Trichy, Tamil Nadu, India, E-mail: brithvivaduganathan@gmail.com

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1. REVLIMID (LENALIDOMIDE)

1.1. Company
Celgene; Approved by June 2013

1.2. Treatment Area
Mantle cell lymphoma

1.3. General Information
Revlimid (lenalidomide), a thalidomide analogue, is an immunomodulatory agent specifically indicated for the treatment of patients with mantle cell lymphoma (MCL) whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib. The recommended dose in this population is 25 mg/day orally on Days 1-21 of repeated 28-day cycles for relapsed or refractory mantle cell lymphoma. Treatment should be continued until disease progression or unacceptable toxicity.

1.4. Mechanism of Action
Revlimid (lenalidomide) is an analogue of thalidomide with immunomodulatory, antiangiogenic, and antineoplastic properties. Lenalidomide inhibits proliferation and induces apoptosis of certain hematopoietic tumor cells including multiple myeloma, mantle cell lymphoma, and myelodysplastic syndromes in vitro. Lenalidomide causes a delay in tumor growth in some in vivo nonclinical hematopoietic tumor models including multiple myeloma. Immunomodulatory properties of lenalidomide include activation of T cells and natural killer (NK) cells, increased numbers of NKT cells, and inhibition of pro-inflammatory cytokines (e.g., TNF-a and IL-6) by monocytes.

1.5. Side Effects
Adverse events associated with the use of Revlimid for mantle cell lymphoma may include: neutropenia, thrombocytopenia, fatigue, diarrhea, anemia, nausea, cough, pyrexia, rash, dyspnea, pruritus, constipation, peripheral edema, and leucopenia.

2. RIXUBIS (COAGULATION FACTOR IX (RECOMBINANT)

2.1. Company
Baxter International; Approved by June 2013

2.2. Treatment Area
Routine prophylaxis and control of hemophilia B

2.3. General Information
Rixubis is supplied as a powder for reconstitution into a solution for intravenous infusion. The initial recommended dose is based on the following formula: Initial Dose = body weight (kg) x desired factor IX increase (% or IU/dL) x reciprocal of observed recovery (IU/dL per IU/kg). The dose for previously treated patients is 40 to 60 international units per kg twice weekly. Titration of dose may be necessary depending upon the individual patient's age, bleeding pattern, and physical activity.

2.4. Mechanism of Action
Rixubis (Coagulation Factor IX (Recombinant)] is a recombinant factor IX (rFIX) protein. It is specifically indicated for the control and prevention of bleeding episodes, perioperative management and routine prophylaxis to prevent or prevent or reduce the frequency of bleeding episodes in adults with hemophilia B.

2.5. Side Effects
Adverse events associated with the use of Rixubis include: dysgeusia, pain in extremity, positive test for furin antibody

3. VIBATIV (TELAVANCIN)

3.1. Company
Theravance; Approved by June 2013

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3.2. Treatment Area
Hospital-acquired and ventilator-associated bacterial pneumonia caused by *staph aureus*

3.3. General Information
Vibativ (telavancin) is specifically indicated for the treatment of adult patients with hospital-acquired and ventilator-associated bacterial pneumonia (HABP/VABP), caused by susceptible isolates of *Staphylococcus aureus* (including methicillin-susceptible and -resistant isolates). Vibativ should be reserved for use when alternative treatments are not suitable. It is supplied as a solution for intravenous infusion. The recommended dose is 10 mg/kg administered over a 60-minute period in patients >18 years of age by intravenous infusion once every 24 hours for 7 to 21 days. The duration of therapy should be guided by the severity of the infection and the patient's clinical progress.

3.4. Mechanism of Action
Vibativ (telavancin) is a semisynthetic, lipoglycopeptide antibiotic. It inhibits cell wall biosynthesis by binding to late-stage peptidoglycan precursors, including lipid II. Telavancin also binds to the bacterial membrane and disrupts membrane barrier function.

3.5. Side Effects
Adverse events associated with the use of Vibativ include: diarrhea, infusion-related reactions

4. XGEVA (DENOSUMAB)

4.1. Company
Amgen; Approved by June 2013

4.2. Treatment Area
Giant cell tumor of bone

4.3. General Information
Xgeva (denosumab) is a human IgG2 monoclonal antibody that binds to human RANKL. Increased osteoclast activity, stimulated by RANKL, is a mediator of bone pathology in solid tumors with osseous metastases. It is specifically indicated for the treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity. The recommended dose for giant cell tumor of the bone is 120 mg administered every 4 weeks with additional 120 mg doses on Days 8 and 15 of the first month of therapy. Administer subcutaneously in the upper arm, upper thigh, or abdomen.

4.4. Mechanism of Action
Xgeva (denosumab) binds to RANKL, a transmembrane or soluble protein essential for the formation, function, and survival of osteoclasts, the cells responsible for bone resorption. Increased osteoclast activity, stimulated by RANKL, is a mediator of bone pathology in solid tumors with osseous metastases. Similarly, giant cell tumors of bone consist of stromal cells expressing RANKL and osteoclast-like giant cells expressing RANK receptor, and signaling through the RANK receptor contributes to osteolysis and tumor growth. Xgeva prevents RANKL from activating its receptor, RANK, on the surface of osteoclasts, their precursors, and osteoclast-like giant cells.

4.5. Side Effects
Adverse events associated with the use of Xgeva for giant cell tumor of the bone include: arthralgia, headache, nausea, back pain, fatigue, and pain in extremity

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